

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

REMARKS

This Amendment is responsive to the Office Action dated February 28, 2006. Applicant has renumbered original claims 34-49 to be claims 33-48 due to the absence of any original claim numbered 33. All claims are referred to herein according to the new claim numbers. The Examiner's remarks that refer to claims numbers have been also changed accordingly. Applicant has amended claims 1, 2, 4, 8, 9, 12-14, 18-20, 22, 27, 30, 33-48. Claims 49-54 have been added. Claims 1-54 are pending.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

In the Office Action, the Examiner rejected claims 8-14 and 19-48 under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has amended claims 8, 9-14, 19, 20, 30, 33, and 39-47. Applicant submits that the claims, as amended, meet the requirements of section 112, second paragraph.

With respect to claim 19, the processor is defined by the functionality recited in the claim. Hence, the processor in original claim 1 was defined as receiving a command, regardless of any device that sends the command. For purposes of definiteness under section 112, second paragraph, it is unclear how the phrase "adapted to" would make this meaning any more clear, or how the claim would be any less clear without such a phrase. In any event, the amendments to claim 19 should render moot the rejection under section 112, second paragraph.

With respect to claim 36 (as apparently intended by the Examiner), one of ordinary skill in the art would have no difficulty ascertaining that the implantable medical device does not form part of the invention specified in this claim. Rather, claim 36 defines the medical device in terms of its incorporation of a programming device that communicates with an implantable medical device. The requirement that the programming device communicate with an implantable medical device does not likewise require that the implantable medical device form part of the invention specified in this claim. Applicant respectfully requests withdrawal of this rejection.

With respect to claims 39 and 40 (as apparently intended by the Examiner), there is no question that the claimed invention, as specified in the claims, does not include a person. To the contrary, the claims specify a computer-readable medium comprising instructions that cause a processor to receive information from a user, i.e., indications of an event. No aspect of the

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

invention of claims 39 and 40 recites a person. Nor does the configuration of a processor to receive user input, as claimed, constitute the claiming of a person. Applicant respectfully requests withdrawal of this rejection.

With respect to claims 38-48, it is clear that Applicant is claiming a computer-readable medium comprising instructions that cause a processor to perform various activities. In this sense, claims 38-48 recite an article of manufacture. The format of claims 38-48 generally conforms to the well-accepted format found acceptable by the Court of Appeals for the Federal Circuit in the case of *In re Beauregard*, 53 F.3d 1583 (Fed. Cir. 1995). Applicant respectfully requests withdrawal of this rejection.

Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-10, 12, 15, 18-29, 35, 37-46 and 48 under 35 U.S.C. 102(b) as being anticipated by Sheldon (U.S. 5,593,431).

Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Sheldon fails to disclose each and every feature of the rejected claims, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claims 1, 19 and 38 require defining an event, monitoring therapy delivered by a medical device during occurrence of the defined event, generating therapy information based on the monitored therapy, associating the therapy information with the defined event, subsequently detecting the defined event, and providing therapy to a patient via the medical device according to the therapy information in response to the detection. The Sheldon reference fails to disclose or suggest all of the elements of the independent claims, as amended.

Sheldon discloses a method and apparatus for detecting the physical posture of a patient's body using accelerometers. According to Sheldon, the detected posture may be used to control the delivery of cardiac stimulation therapy. For example, the Sheldon device may adjust the pacing rate of a rate responsive pacemaker in response to a detected posture. Hence, Sheldon contemplates control of pacing therapy in response to detected posture.

In contrast to claims 1, 19 and 38, Sheldon does not suggest monitoring therapy delivered by a medical device during occurrence of a defined event, as set forth in claims 1, 19, and 38, and

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

generating therapy information based on the monitored therapy. The Sheldon device is responsive to detected posture to control stimulation therapy in a prescribed manner. However, Sheldon makes no mention of the monitoring of therapy delivered during a defined event. In this regard, the Office Action referred to column 12, line 55, of Sheldon, which discusses control (but not monitoring) of pacing therapy in response to detected posture.

Nor does Sheldon suggest subsequently detecting the defined event, and providing therapy to a patient via the medical device according to the therapy information in response to the detection, as recited by claims 1, 19, and 38. Sheldon describes control of therapy based on detected posture, but makes no mention of providing therapy for a subsequently detected event according to therapy information that relates to monitored therapy delivered to a patient during a previous event.

In view of such differences, Sheldon fails to support a *prima facie* case of anticipation with respect to the invention defined by claims 1, 19 and 38. Sheldon also fails to disclose or suggest the limitations of various dependent claims, some of which are discussed below.

Claims 2, 20 and 39, for example, require receiving indications of an event from a user. Sheldon fails to suggest detection of a defined event by receiving an indication of the event from the user. Sheldon states that "activity and body position signals may be stored and/or used to monitor and effect the delivery of a therapy to the patient, e.g. by controlling the pacing rate of a rate responsive pacemaker."¹ Contrary to the requirements of claims 2, 20 and 39, however, Sheldon does not suggest the use of event indications from a user to detect a defined event. Instead, Sheldon relies on the accelerometers to detect events without user event indications.

With respect to claims 8, 27 and 43, Sheldon fails to describe associating recording a value of a therapy parameter that controls delivery of therapy by the medical device in response to a command from a user to enter a learning mode. The Examiner asserted that a change in posture constitutes such a command. The Examiner's interpretation of this aspect of the Sheldon reference is unreasonable. There is no suggestion in Sheldon that a change in posture would be used as a command to enter a learning mode. Moreover, Sheldon does not even contemplate a learning mode in which a therapy parameter that controls delivery of therapy is recorded.

¹ Sheldon, Abstract

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

According to Sheldon, posture may be detected and used to control pacing therapy. However, posture is not itself a therapy parameter, nor a learning mode command from a user. The passage identified by the Examiner in rejecting claims 8, 27 and 43 from Sheldon does not even address controlling delivery of therapy. Instead, at Col. 10, line 17, Sheldon discusses normalizing the output signals of accelerometers. The accelerometer output signals are not therapy parameters, but rather sensed signals. On the contrary, an example of a therapy parameter would be an amplitude, pulse width, or pulse rate.

Moreover, the Examiner's analysis seems to require that the detected posture in Sheldon satisfy two different requirements of Applicant's claims. In particular, the Examiner apparently has interpreted detected posture as both a therapy parameter and a detected event. A detected posture cannot logically satisfy both limitations. If posture is interpreted as both a therapy parameter that controls delivery of therapy and a defined event, for example, it is unclear why therapy information would be associated with a defined event? Or, alternatively, why would posture need to be associated with posture? This discrepancy undermines the logic in the Examiner's analysis, and further highlights the differences between Sheldon and the invention defined by claims 8, 27 and 43.

Claims 9, 10, 28, 29, 44 and 45 require recording a change to the therapy parameter made by the user. In support of the rejection, the Examiner stated that "various postures are recorded, so 'a change to the parameter' is recorded."² The Examiner's interpretation of "therapy parameter" is unreasonable. As mentioned above, in Sheldon, a detected posture does not constitute a therapy parameter. Instead, Sheldon describes adjustment of therapy parameters based on detected posture. In addition, Sheldon reference makes no mention of the recording of a change to the therapy parameter. Therefore, Sheldon fails to anticipate the requirements of claims 9, 10, 28, 29, 44 and 45.

Claim 12 requires that the medical device is an implantable medical device, and recording the change to the therapy parameter includes receiving the change to the therapy parameter made by the user via a programming device. Again, in Sheldon, posture is not a therapy parameter, and Sheldon fails to provide any description related to recording the change to the therapy parameter. Moreover, even if posture were a therapy parameter, Sheldon would not receive a posture change

² Office Action, Page 5.

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

made by a user via a programming device. Rather, the Sheldon device detects posture changes via accelerometers.

Claims 15 and 34 require suspending delivery of therapy. The Examiner rejected these claims based on the assertion that an "escape interval" described by Sheldon is identical to suspending delivery of therapy. Applicant disagrees with the Examiner. The escape interval does not relate to suspension of therapy, but rather defines the therapy in terms of the setting the base pacing rate.

Dependent claims 3-7, 18, 21-26, 36-37, 40-42, 46 and 48 are in allowable for at least the reasons above with respect to independent claims 1, 19 and 38.

Sheldon fails to disclose each and every limitation set forth in claims 1-10, 12, 15, 18-29, 34, 36-45 and 48. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-10, 12, 15, 18-29, 34, 36-45 and 48 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 14, 16, 17, 31-33, 46 and 47 under 35 U.S.C. 103(a) as being unpatentable over Sheldon in view of Schallhorn (U.S. 6,120,467). The Examiner also rejected claims 11, 13, 30 and 35 under 35 U.S.C. 103(a) as being unpatentable over Sheldon.

Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 14, 31 and 47 require that recording the value of the parameter includes receiving the value of the parameter and a time from the user, and providing therapy to a patient according to the therapy information includes changing delivery of therapy at a time subsequent to detection of the event according to the value and time received from the user. Sheldon fails to suggest receiving a value of the parameter and a time from the user or providing therapy according to the value and time received from the user.

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

The Examiner stated that Sheldon does not expressly disclose receiving a time from the user. However, the Examiner stated that “[i]t is well known in the art to provide user-customizable time intervals to provide a desired level of hysteresis in signal acquisition and presenting acquired data to a clinician to enable the clinician to modify parameters or make a diagnosis.” On this basis, the Examiner concluded that it would have been obvious to modify the Sheldon device. The Examiner’s conclusion of obviousness is improper.

First, the Examiner cited no prior art teaching for the proposition that it is well known in the art to provide user-customizable time intervals, to the extent it is even relevant to the requirements of the claims. More importantly, the Examiner did not cite any prior art teaching that suggested receiving a parameter value and a time from a user, which is actually recited in the claims.

In either case, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness.³ In doing so, the Examiner must determine whether the prior art provides a “teaching or suggestion to one of ordinary skill in the art to make the changes that would produce” the claimed invention.⁴ A *prima facie* case of obviousness is established only when this burden is met.

The Court of Appeals for the Federal Circuit has addressed the evidentiary standard required to uphold an obviousness rejection.⁵ Specifically, the Federal Circuit stated: “[the] factual question of motivation is material to patentability, and (can) not be resolved on subjective belief and unknown authority.⁶ This finding must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.⁷ Deficiencies in the evidentiary record cannot be cured by general conclusions such as “general knowledge” or “common sense.”⁸

Accordingly, the Examiner cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.⁹ Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with

³ *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

⁴ *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

⁵ *In re Lee*, 61 USPQ2d 1430, (CAFC 2002).

⁶ *Id.* at 1434.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

ordinary skill in the art to incorporate the features of claims 14, 31 and 47, the claims should be allowed.

Second, the Examiner's reference to hysteresis in signal acquisition is nonsensical and bears no relationship whatsoever to the actual requirements of claims 14, 31 and 47. Such claims require receiving a parameter value and a time from a user, and changing delivery of therapy at a time subsequent to detection of the event according to the value and time received from the user. Hence, the features recited in claims 14, 31, and 47 relate to changing therapy in response to a parameter value and time received from a user, and have absolutely to do with signal acquisition or hysteresis. In view of the lack of any pertinent prior art teaching of record, it is unclear how the limitations of claims 14, 31 and 47 would have been obvious to one of ordinary skill in the art.

Claims 17 and 33 require presenting the defined event as a marker within a timing diagram. The Examiner characterized FIG. 15 of Sheldon as showing the derivation of events with markers over time. FIG. 15 of Sheldon provide no such teaching. FIG. 15 shows correlation of accelerometer output with patient posture. However, there is no mention of a timing diagram or markers within the Sheldon disclosure, nor any suggestion of the desirability of presenting defined events as markers in a timing diagram. Rather, FIG. 15 merely shows how mean voltage output levels from accelerometers can be used to distinguish different postures. Nothing in FIG. 15 constitutes an event marker. Moreover, the graph of FIG. 15 is not a timing diagram, but rather a graph of a voltage level over time.

Claims 11 and 30 require changing the therapy parameter at a time subsequent to detection of the event according to the recorded changes to the therapy parameter. The Examiner acknowledged that Sheldon fails to disclose such features, but cited Schallhorn as teaching such a feature. The Examiner has misinterpreted Schallhorn. Schallhorn indicates that a "patient activity level recorder and a patient therapy adjustment recorder are provided to obtain a historical representation of patient activity levels and therapy changes...for later retrieval."¹⁰ FIG. 5 of Schallhorn illustrates selection of a setting that offers a more beneficial therapy based upon feedback from the patient and recorded activity levels.

However, the combination of Schallhorn and Sheldon would not result in the required elements of the claims. Schallhorn makes no mention of changing a therapy parameter at a time

¹⁰ Schallhorn, Abstract.

Application Number 10/691,917
Amendment in Response to Office Action mailed February 28, 2006

subsequent to detection of an event according to recorded changes in therapy. Instead, Schallhorn describes the presentation of patient activity data and patient therapy changes to permit review of such data so that a physician may modify patient therapy. Accordingly, Schallhorn provides no teaching that would have suggested the desirability of modification of the Sheldon device to conform to the requirements of claims 11 and 30.

Dependent claims 13, 16, 32, 35 and 46 are in allowable for at least the reasons above with respect to independent claims 1, 19 and 38 and dependent claims from which they depend.

For at least these reasons, the Examiner has failed to establish a *prima facie* case of unpatentability of Applicant's claims 11, 13-14, 16, 17, 30-33, 35 and 46-47 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

New Claims:

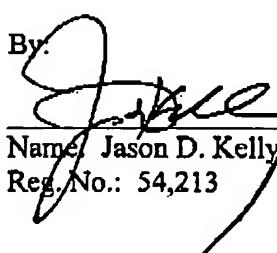
Applicant has added claims 49-54 to the pending application. No new matter has been added in the new claims. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. No new matter has been added by the new claims.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: July 14, 2006

By:


Name: Jason D. Kelly
Reg. No.: 54,213

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102